UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PFIZER INC.,

Plaintiff,

-against-

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

1:20-cv-4920 (MKV)

OPINION AND ORDER GRANTING DEFENDANT'S MOTION TO DISMISS AND FOR SUMMARY JUDGMENT AND DENYING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

MARY KAY VYSKOCIL, United States District Judge:

In this case, Plaintiff Pfizer Inc. seeks declarations that one or both of two potential co-pay assistance programs, if implemented, would not violate the federal Anti-Kickback Statute ("AKS"), and Beneficiary Inducement Statute ("BIS"). Before this case was filed, the federal government, acting through the Office of the Inspector General ("OIG") of the Department of Health and Human Services ("HHS"), reviewed the programs and notified Pfizer that at least one of the of them could violate the statutes if implemented as Pfizer intended. The consequences of a violation could be dire for Pfizer, potentially including civil or criminal monetary penalties and exclusion of all Pfizer products from eligibility for coverage under Medicare and Medicaid. *See* 42 U.S.C. §§ 1320a-7, 1320a-7a, 1320a-7b.

Before the Court are cross-motions from the parties, both seeking judgment in their favor.[1] Following careful review of the parties' submissions and having heard oral argument on the motions, Defendants' motion is GRANTED, and Plaintiff's motion is DENIED.

FACTUAL BACKGROUND AND PROCEDURAL HISTORY

A. Pfizer's Drug and Proposed Programs

The Parties substantially agree on the facts relevant to this dispute. In light of that, the Court cites to the Complaint [ECF No. 1] ('Cpl."). For facts not contained in the complaint, the Court cites the administrative record of proceedings before the Department of Health and Human Services [ECF No. 46] ("AR").

Pfizer produces and markets a drug called tafamidis[2] to treat Transthyretin Amyloid Cardiomyopathy ("ATTR-CM"). Cpl. ¶ 1. ATTR-CM is a rare, progressive condition that causes deposits of amyloid protein to be deposited in the heart muscle. Cpl. ¶ 25. As a result, the afflicted person may experience progressive heart failure, culminating in being unable to perform even basic life tasks. Cpl. ¶ 25. Patients with diagnosed ATTR-CM have a life expectancy of 2-3.5 years after diagnosis. Cpl. ¶ 25. There are estimated to be approximately 100,000-150,000 people afflicted with ATTR-CM in the United States, with higher concentrations among the elderly and among African American males. Cpl. ¶ 3, 27. Tafamidis

[1] The filings relevant to the parties' motions are 1) Pfizer's Memorandum of Law in Support of the Motion for Summary Judgment [ECF No. 34] ("Pfizer Br."), 2) Defendants' Memorandum of Law in Opposition to Pfizer's Motion and in Support of the Motion to Dismiss and for Summary Judgment [ECF No. 45] ("HHS Br."); 3) Pfizer's Reply Memorandum of Law and Opposition to Defendants' Motion [ECF No. 53] ("Pfizer Reply"), and 4) Defendants' Reply Memorandum of Law [ECF No. 57] ("HHS Reply"). Since briefing was complete, the parties filed several letters bringing supplemental authority to the Court's attention and addressing other issues [ECF Nos. 58-59, 66, 75-76, 83]. The Court also granted leave to the National Minority Quality Forum and the Pharmaceutical Research and Manufacturers of America to file briefs in the case as *amicus curiae* [ECF No. 65] ("NMQF Br."); [ECF No. 62] ("PhRMA Br.").

[2] As explained in the complaint, tafamidis actually refers to two drugs sold under the brand names Vyndaqel and Vyndamax. *See* Cpl. ¶ 1. They are the same for the purposes of this case and are referred to collectively as "tafamidis."

is currently the only FDA-approved drug to treat ATTR-CM. Cpl. ¶¶ 42-43. The drug was developed through extensive testing and trials over the course of nearly 20 years and benefitted from "orphan drug" classification from the FDA.[3] Cpl. ¶¶ 28-41.

Because ATTR-CM disproportionately affects older Americans, a large proportion of the population eligible for treatment with tafamidis receives Medicare. Cpl. ¶¶ 45, 55. Medicare Part D is the portion of Medicare concerned with outpatient prescription drugs like tafamidis. Cpl. ¶ 45. An integral part of Medicare Part D is the cost-sharing baked into the scheme. Through a complicated scheme, and as relevant to the drugs in this case, Medicare Part D participants are responsible for certain deductibles and co-pays based on the cost of the drugs doctors prescribe them. In 2020, for example, Medicare Part D participants were responsible for a $435 deductible before they received any assistance. Cpl. ¶ 46. Then, a participant has to contribute 25% of all costs until the total costs of his or her medications reached the "catastrophic coverage" threshold (in 2020, $9,303). Cpl. ¶ 46. In real numbers, this means that a Medicare Part D enrollee who took only brand-name drugs was responsible for $2,652 before receiving "catastrophic coverage." Upon reaching that threshold, the participant is responsible for 5% of all remaining costs, with no upper limit. Cpl. ¶ 46.

In order to assist lower income Medicare Part D participants, and to dissuade patients from foregoing coverage, the federal government provides co-pay support for any person whose income is less than 150% of the federal poverty level. Cpl. ¶ 49. Surveys of Medicare Part D participants suggest that approximately 29% of all Part D participants fall in this range. Cpl. ¶ 49. However, Pfizer suggests that the upper limit for this additional support is too low, and

[3] Orphan drug classification is a special status that the FDA may grant a proposed/developing drug to treat a rare disease and qualifies the developer for incentives related to the drug development. Cpl. ¶ 33 (citing 21 U.S.C. § 360bb, and then citing 21 C.F.R. Part 316).

fails to include all Medicare recipients who otherwise cannot afford the Part D cost-sharing.[4] The company offers survey evidence that at least 25% of new Part D enrollees will forego prescriptions or care if they are asked to pay more than $50 and that almost 50% of cancer patients asked to pay more than $2,000 out of pocket did not fill prescriptions. Cpl. ¶ 51.

Tafamidis costs $225,000 per year. AR 2, 12, 125. As a result of the payment scheme outlined above, Medicare Part D participants would pay approximately $13,000 per year in cost-sharing, absent assistance, for the medication. Cpl. ¶ 52. Pfizer suggests that while affluent patients may be able to afford that amount, there is a substantial number of "middle-income" patients who cannot pay these prices. Cpl. ¶¶ 53-55. Indeed, Pfizer states that even if tafamidis's price was cut in half, patients would still be required to pay more than $8,000 per year. Cpl. ¶ 53. In light of this substantial barrier to treatment, Pfizer sought to create its own co-pay assistance programs. Cpl. ¶ 7.

Pfizer has proposed two programs in which it would provide additional assistance to patients in order to limit their costs to a maximum of $35 a month. First, it proposes a "Direct Copay Assistance Program" (the "Direct Program") under which Pfizer would provide funds directly to the patient. Cpl. ¶ 61. Pfizer proposes that to be eligible for assistance in the Direct Program, "patients must: (1) be prescribed tafamidis for an on-label (approved) indication, that is, ATTR-CM; (2) be United States residents; and (3) meet program criteria for financial need tailored to address the burden otherwise faced by middle-income patients who are unable to access other available resources." Cpl. ¶ 62. Pfizer states that it would not advertise the program or use it to solicit patients before the drug is prescribed. Cpl. ¶ 63. Second, Pfizer proposes an

[4] The median annual income for Medicare beneficiaries is approximately $29,650. *See* Pfizer Br. at 12. However, 150% of the federal poverty level only reaches beneficiaries making up to approximately $19,140 (for an individual). Cpl. ¶ 49.

assistance program involving a Pfizer-supported charity (the "Charity Program"). For this, Pfizer would fund an existing independent charity to develop its own guidelines and programs to assist Part D participants with payments for tafamidis. Cpl. ¶ 70. While Pfizer would communicate with the charity about funding needs, the charity would otherwise operate independently and develop its own guidelines for aid programs. Cpl. ¶ 72.

Relevant to this case and these programs, Pfizer is currently subject to a "Corporate Integrity Agreement" signed as a part of a $23.9 million settlement of earlier AKS claims related to a purportedly independent charity Pfizer attempted to use as a part of a different co-pay assistance program. *See* AR 480, 483. The agreement, signed in 2018, provides that for five years, Pfizer will contribute to an independent charity co-pay assistance program only if:

> a. . . . Pfizer has not made and shall not make . . . suggestions or requests to the Independent Charity PAP about the identification, delineation, establishment, or modification of disease state funds;
>
> b. Pfizer does not and shall not exert any direct or indirect influence or control over the Independent Charity PAP's process or criteria for determining eligibility of patients who qualify for its assistance program;
>
> [. . .]
>
> d. Pfizer does not and shall not provide donations for a disease state fund that covers only a single product or that covers only Pfizer's products.

AR at 501-02.

B. The Administrative Review

To combat fraud and abuse in connection with Medicare and Medicaid, Congress enacted the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"). In relevant part, that statute prohibits:

> knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce [a] person . . . to purchase . . . or arrange for or recommend purchasing . . . any good, facility, service, or item for which payment

> may be made in whole or in part under a Federal health care program [defined elsewhere as Medicare and Medicaid]. 42 U.S.C. § 1320a-7b(b)(2)(B).

Violations of the AKS include criminal and civil sanctions, up to and including a pharmaceutical company's exclusion entirely from federal reimbursement for any of its medications. Cpl. ¶ 122; *see also* 42 U.S.C. § 1320a-7(b)(7) (permitting the Secretary of Health and Human Services to "exclude . . . from participation in any Federal health care program" any person or entity that violates the AKS).

A similar regime is contained within the Beneficiary Inducement Statute ("BIS"), 42 U.S.C. § 1320a-7a. In relevant part, this statute subjects to a civil penalty any entity that: "offers to or transfers remuneration to any individual eligible for benefits under [a federal or state healthcare program] . . . that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [a federal or state healthcare program]." 42 U.S.C. § 1320a-7a(a)(5). Certain definitions and exceptions apply only to the BIS and not to the AKS, including specifically a definition of "remuneration" that specifically excludes "waiver of coinsurance and deductible amounts" except in limited circumstances. 42 U.S.C. § 1320a-7a(i)(6).

Because the threat of sanctions and criminal charges for violations of the AKS and BIS are severe, Congress enacted a process by which entities can seek advisory opinions from the HHS OIG about whether an anticipated program or course of action would violate either or both of the statutes. 42 U.S.C. 1320a-7d(b). Any resulting advisory opinion is a binding administrative action on both the Government and the requesting party. 42 U.S.C. § 1320a-7d(b)(4)(A).

In 2005 and 2014, the HHS OIG published guidance documents about what kinds of assistance programs violate the AKS or BIS and how companies can ensure compliance with the law. Cpl. ¶ 94. In the first guidance document, HHS OIG stated that assistance programs like the Direct Program and Charity Program that Pfizer proposes, "pose a heightened risk of fraud and abuse" under the AKS, particularly because they "shield [Medicare Part D] beneficiaries from the economic effects of drug pricing, thus eliminating a market safeguard against inflated prices." 70 Fed. Reg. 70,623, 70,626 (Nov. 22, 2005). This concern was reiterated in 2014, when the HHS OIG noted that assistance programs provide pharmaceutical companies like Pfizer with "the ability to subsidize copayments for their own products [and] may encourage manufacturers to increase prices, potentially at additional cost to Federal health care programs and beneficiaries who are unable to obtain copayment support." 79 Fed. Reg. 31,122 (May 30, 2014). In both the 2005 and 2014 guidance however, the agency noted that an assistance fund that "[targets] only one drug or drugs made by one manufacturer would not, standing alone, be determinative of an anti-kickback statute violation." Cpl. ¶ 94 (first citing 70 Fed. Reg. 70,623-03, 70,627 n.19 (Nov. 22, 2005); and then citing 79 Fed. Reg. 31,120, 31,122 (May 30, 2014)).

In light of this previous guidance, Pfizer sought an advisory opinion about its anticipated tafamidis programs in June 2019. Cpl. ¶ 103. Less than two months later, OIG rejected the request, stating that it was "not able to issue an advisory opinion" as to the Charity Program "because 'the same or substantially the same course of action is under investigation, or has been the subject of a[n] [enforcement] proceeding involving [HHS] or another governmental agency.'" Cpl. ¶ 104. After further consultation with OIG, Pfizer resubmitted the request, seeking an opinion only as to the Direct Program and excluding the Charity Program. Cpl. ¶ 104. In December 2019, OIG informed Pfizer that it had reached "an unfavorable opinion" of

the Direct Program (*i.e.* that it would violate the AKS), and that OIG would issue a binding advisory opinion to that effect if Pfizer did not voluntarily withdraw the request. Cpl. ¶ 105. Pfizer sought a second meeting with OIG following this notification and submitted additional clarifying information about the Direct Program. Cpl. ¶¶ 106-07. Nonetheless, OIG again informed Pfizer in May 2020 that it had reached an unfavorable view of the Direct Program and that a binding advisory opinion would issue if Pfizer did not withdraw the request. Cpl. ¶ 108. Pfizer filed this case shortly thereafter. After the case was filed, OIG issued a binding Advisory Opinion regarding the Direct Program. *See* AR 141-68.

The Advisory Opinion issued by the HHS OIG concluded that the Direct Program would not violate the BIS, but that it could violate the AKS "if the requisite intent to induce or reward referrals for, or purchases of, items and services reimbursable by a Federal health care program were present."[5] AR 142. The opinion largely focused on the intent of the program as the hallmark for an AKS violation, noting that the Direct Program might "operate as a *quid pro quo*—[Pfizer] would offer remuneration . . . to the beneficiary in return for the beneficiary purchasing" tafamidis. AR 154. Significantly, the OIG observed that the program appeared designed to induce "a Medicare beneficiary [who] otherwise may be unwilling or unable to purchase [tafamidis] due to his or her cost-sharing obligations, which are driven by the list price, . . . to purchase" the drug. AR 155. The HHS OIG further noted that the Direct Program presented "more than a minimal risk of fraud and abuse," as a result of Pfizer's elimination of patient cost-sharing, "one of the key pricing controls" inherent in Medicare Part D. AR 156,

[5] Because of this conclusion, the Court's review of the issues related to the Direct Program do not consider the BIS, as all parties agree that it would not be violated by the program.

158. The claims in Plaintiff's complaint, in part, seek a declaration eliminating the potential that the Direct Program ever could violate the AKS.

C. Procedural History of This Case

The complaint in this case contains four causes of action concerning both the Direct Program and the Charity Program. First, Pfizer seeks a declaration that the Direct Program and the Charity Program do not violate the AKS or the BIS. Cpl. ¶¶ 137-143 (Count I). Second, Pfizer seeks a declaration that OIG's guidance regarding the Charity Program would infringe on Pfizer's First Amendment rights. Cpl. ¶¶ 144-150 (Count II). Third, Pfizer seeks a declaration that OIG's guidance regarding the Charity Program would violate the Fifth Amendment Due Process Clause. Cpl. ¶¶ 151-57 (Count III). Finally, Pfizer seeks an order vacating HHS's guidance and advisory opinion as contrary to law under the Administrative Procedure Act ("APA"). Cpl. ¶¶ 158-168 (Count IV).

The parties filed cross-motions for judgment on the claims, and Defendants, alternatively, filed for dismissal of certain of the claims. In support of dismissal of the complaint, Defendants argue that the Court lacks jurisdiction to hear the case as related to the Charity Program because there is no claim, other than those for a declaratory judgment, related to it. Since the Declaratory Judgment Act does not provide an independent basis for jurisdiction, HHS argues that the claims should be dismissed as to the Charity Program. *See* HHS Br. at 22-23. Both Pfizer and HHS then seek summary judgment on the declaratory judgment and substantive APA claims related to the Direct Program and, to the extent they are not dismissed, those related to the Charity Program. The Court has heard oral argument on the cross-motions. *See* Transcript of Summary Judgment Hearing [ECF No. 80] ("Tr.").

After the Court held oral argument on the cross-motions, Plaintiff filed a letter seeking leave to file a motion pursuant to Federal Rule of Civil Procedure 41(a)(2) to dismiss Counts I,

II, and III of its complaint, which would eliminate all claims related to the Charity Program and would limit the case only to Pfizer's claim that the HHS OIG advisory opinion was issued in violation of the APA as not in accordance with law. *See* Letter to Court [ECF No. 78]; Cpl. ¶¶ 158-68. The Government does not object to the request. *See* Letter to Court [ECF No. 79]. However, Rule 41(a)(2) is not absolute and permits voluntary dismissal by order of the Court "upon such terms and conditions as the court deems proper." Fed. R. Civ. P. 41(a)(2).

The Second Circuit has explained that relevant factors to consider in connection with a Rule 41(a)(2) motion include "the plaintiff's diligence in bringing the motion; any 'undue vexatiousness' on plaintiff's part; the extent to which the suit has progressed, including the defendant's effort and expense in preparation for trial; the duplicative expense of relitigation; and the adequacy of plaintiff's explanation for the need to dismiss." *Zagano v. Fordham Univ.*, 900 F.2d 12, 14 (2d Cir. 1990). Pfizer has not explained any "need" to dismiss the claims other than the avoidance of legal issues that otherwise could be fatal to Plaintiff's claims [ECF No. 78 at 1]. Given that the parties already had briefed and argued the issues related to the claims and that the Court already had devoted significant resources to preparing for argument and to resolving all of the issues in the parties' motions, Plaintiff's request for dismissal under Rule 41(a)(2) is denied and the Court proceeds to consideration of all the parties' arguments.

LEGAL STANDARD

A. Rule 12(b) Motion

Defendants first move under Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure for dismissal of Plaintiff's claims related to the Charity Program because the Court lacks subject matter jurisdiction over the claims. A court must dismiss a claim if it "lacks the statutory or constitutional power to adjudicate it." *Morrison v. National Australia Bank Ltd.*, 547 F.3d 167, 170 (2d Cir. 2008) (internal quotation marks omitted), *aff'd*, 561 U.S. 247 (2010).

"The plaintiff bears the burden of proving subject matter jurisdiction by a preponderance of the evidence." *Aurecchione v. Schoolman Transp. Sys., Inc.*, 426 F.3d 635, 638 (2d Cir. 2005). In deciding the motion to dismiss, the Court "must take all facts alleged in the complaint as true and draw all reasonable inferences in favor of plaintiff." *Morrison*, 547 F.3d at 170 (quoting *Natural Resources Defense Council v. Johnson*, 461 F.3d 164, 171 (2d Cir. 2006)).

B. Rule 56 Motion

Both Plaintiff and Defendants move for summary judgment on any claims that survive the motion to dismiss. "Summary judgment is appropriate only when, 'the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" *Ya-Chen Chen v. City Univ. of N.Y.*, 805 F.3d 59, 69 (2d Cir. 2015) (quoting Fed. R. Civ. P. 56(a)). In this case, because the parties are limited to the facts in the administrative record, Plaintiff and Defendants agree that there are no questions of fact in this case. *See* Pfizer Br. at 8, HHS Br. at 11.

In a case challenging administrative agency action, courts must "review *de novo* 'all relevant questions of law' and 'interpret[ations] [of] constitutional and statutory provisions' made by an agency." *Aleutian Cap. Partners, LLC v. Scalia*, 975 F.3d 220, 229 (2d Cir. 2020) (quoting 5 U.S.C. § 706) (alterations in original). Summary judgment is appropriate to finally resolve Plaintiff's claims here. *Aleutian Cap. Partners*, 975 F.3d at 229 ("Where, as here, an APA-based challenge to an agency's action presents a pure question of law, a district court's procedural decision to award summary judgment is generally appropriate." (citing *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083-84 (D.C. Cir. 2001))).

C. The Court's Review of the HHS OIG Actions

The parties disagree about the appropriate deference the Court must give the administrative guidance documents and the advisory opinion here. Defendants note that the

Court should defer entirely to the administrative actions. *See* HHS Br. at 11. Pfizer urges that no deference to the advisory opinion is appropriate and that the HHS guidance on which it is based is entitled only to deference "to the extent the agency's rationale has the power to persuade." Pfizer Br. at 8-9.

Formal deference either to the HHS OIG Advisory Opinion or to other HHS guidance is not appropriate here. Interpretations of law contained in guidance and advisory documents are "entitled to respect" to the extent that those interpretations have the "power to persuade." *Christensen v Harris Cnty.*, 529 U.S. 576, 587 (2000). This deference, stemming from *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), only means that the Court must consider the administrative decision for its "persuasive" value, and not necessarily with any more respect than the Court considers non-binding precedent. *See Georgia v. Public.Resource.Org, Inc.*, __ U.S. __, 140 S. Ct. 1498, 1510 (2020) ("But, as Georgia concedes, the Compendium is a non-binding administrative manual that at most merits deference under *Skidmore v. Swift & Co.* That means we must follow it only to the extent it has the 'power to persuade.' Because our precedents answer the question before us, we find any competing guidance in the Compendium unpersuasive." (internal citations omitted)). Thus, the Court considers the advisory opinion issued by the HHS OIG alongside the parties' arguments but does not weigh it any more heavily than its persuasive value.

DISCUSSION

I. DEFENDANTS ARE ENTITLED TO DISMSSAL OF THE CLAIMS RELATED TO PFIZER'S PROPOSED CHARITY PROGRAM

A. Subject-Matter Jurisdiction

Defendants first argue, in support of dismissal of Pfizer's claims related to the Charity Program, all brought pursuant to the Declaratory Judgment Act, that the Court is without

jurisdiction to hear those claims. Pfizer's first three causes of action seek declarations that the Charity Program does not violate the AKS or BIS (Count I), that application of HHS OIG guidance to the Charity Program would violate Pfizer's First Amendment rights (Count II), and that application of the guidance to the Charity Program would violate the Fifth Amendment right to equal protection held by third parties (Count III). Cpl. ¶¶ 137-57. Because the Declaratory Judgment Act does not independently provide subject matter jurisdiction, absent a substantive claim related to the Charity Program, Pfizer must establish that any declaration related to that program would resolve an actual controversy between the parties. Moreover, even if jurisdiction is proper, Pfizer must satisfy prudential ripeness concerns. While the Court disagrees that it lacks jurisdiction to hear the claims, the Court agrees with Defendants that Pfizer's Charity Program claims do not satisfy the standard for prudential ripeness and must be dismissed.

The Declaratory Judgment Act gives federal courts discretion to "declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). But, it does not operate as an independent grant of jurisdiction, or create a cause of action. *Chevron Corp. v. Naranjo*, 667 F.3d 232, 244 (2d Cir. 2012); *In re Joint E. & S. Dist. Asbestos Litig.*, 14 F.3d 726, 731 (2d Cir. 1993). Rather, the Act's "operation is procedural only—to provide a form of relief previously unavailable." *In re Joint E. & S. Dist. Asbestos Litig.*, 14 F.3d at 731. Absent a substantive claim related to the same dispute, in order to sustain a claim for a declaratory judgment, plaintiffs must provide facts to establish that there is a dispute between the parties that is "'definite and concrete, touching the legal relations of parties having adverse legal interests[]' and that it [is] 'real and substantial' and 'admi[ts] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" *MedImmune, Inc. v.*

Genentech, Inc., 549 U.S. 118 (2007) (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 277, 240-41, 257 (1937)). Otherwise, the Court does not have jurisdiction to consider a claim that simply seeks a declaratory judgment. *Holder v. Humanitarian L. Project*, 561 U.S. 1, 12 (2010).

In connection with the Declaratory Judgment Act, courts also have developed a set of "prudential ripeness" standards that judges must apply when considering whether a claim for a declaratory judgment that might technically satisfy other requirements otherwise nonetheless is not appropriate for review. Specifically, the Court considers: (1) the fitness of the issues for judicial decision; and (2) the hardship to the parties of withholding court consideration. *See Vullo v. Off. of the Comptroller of the Currency*, 378 F. Supp. 3d 271, 283 (S.D.N.Y. 2019). An issue is not fit for adjudication if, on balance, the Court's analysis is contingent on future events that may or may not occur. *In re Combustion Equip. Ass'n Inc. v. EPA*, 838 F.2d 35, 39 (2d. Cir. 1988). The Second Circuit also has set out a more extensive set of factors to review in connection with prudential ripeness:

> (1) whether the judgment will serve a useful purpose in clarifying or settling the legal issues involved; . . . (2) whether a judgment would finalize the controversy and offer relief from uncertainty . . . [3] whether the proposed remedy is being used merely for procedural fencing or a race to res judicata; [4] whether the use of a declaratory judgment would increase friction between sovereign legal systems or improperly encroach on the domain of a state or foreign court; and [5] whether there is a better or more effective remedy."

Dow Jones & Co., Inc. v. Harrods Ltd., 346 F.3d 357, 359-60 (2d Cir. 2003).

1. The Court Has Jurisdiction to Consider the Declaratory Judgment Claims Even in the Absence of Another Substantive Claim about the Charity Program

Whether the Court has jurisdiction to consider a claim under the Declaratory Judgment Act turns in part on whether there is a substantive claim related to the same subject matter. Here, while Pfizer's APA claim seeks "a judgment setting aside OIG's determination that the Proposed Copay Assistance Programs [defined as both the Direct and Charity Programs] implicate the

AKS or BIS," Cpl ¶ 168, there is no possible claim related to the Charity Program. The HHS OIG never decided that the Charity Program violated the AKS and the BIS. As noted above, because another investigation into a substantially similar course of action was pending, OIG declined Pfizer's request for an opinion on the Charity Program.

The APA claim does not challenge that decision, nor could it. As an initial matter, the HHS OIG took no final agency action with respect to the Charity Program, precluding this Court's review. *See* 5 U.S.C. § 704. More importantly, the HHS OIG decision to refuse to consider Pfizer's initial advisory opinion request appears to be substantively correct. HHS regulations prohibit the OIG from issuing an advisory opinion where "[t]he same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency." 42 C.F.R. § 1008.15(c)(2). Defendants cite this regulation and other non-Pfizer-related investigations (and Pfizer's still-in-effect 2018 Corporate Integrity Agreement) as prohibiting any action with respect to the Pfizer Charity Program. HHS Br. at 29-30. Defendants also point to the Corporate Integrity Agreement as independently barring Pfizer's attempt to seek approval for a second similar program, including because it waived some of the rights it seeks to assert here. *See* HHS Br. 26-27, 30-31. Absent a challenge to the regulation barring the HHS OIG from considering requests for advisory opinions in this circumstance or the application of that regulation to Pfizer here, which Pfizer does not allege, there is not a standalone APA claim about the Charity Program. Ordinarily, this would mean that Pfizer's declaratory judgment claim also fails for failure to allege a concrete case or controversy.

But, Pfizer argues that a concrete dispute between the parties exists in connection with the claims for declaratory judgments concerning the Charity Program. Pfizer Reply at 23. In

support of that argument, the company points to cases where courts issued declaratory judgments in connection with "pre-enforcement" review of possible prosecutions or legal actions. Most of the cases Pfizer cites arise in the context of First Amendment, *i.e.* where a speaker was threatened with arrest or prosecution before they spoke. *See, e.g.*, *Susan B. Anthony List v. Driehaus*, __ U.S. __, 134 S. Ct. 2334 (2014) (permitting pre-enforcement review of a potential election spending prosecution where state election commission had received a referral for prosecution, but no case was filed); *Holder*, 561 U.S. at 12 (2010) (permitting pre-enforcement review of statute criminalizing donations to organizations alleged to be connected to terrorism where court found a "genuine threat of imminent prosecution"). In short, these cases present concrete actual controversies because of the real, stated threat of the legal action against the plaintiff.

Pfizer frames its injury, as it relates to the Charity Program, at least in part as an issue of speech. *See* Cpl. ¶¶ 132-34. Pfizer claims that its spending on the Charity Program would fall within the "speech incident to charitable giving" recognized by the Supreme Court. Cpl. ¶ 132 (citing *McCutcheon v. Fed. Election Comm'n*, 572 U.S. 185, 203 (2014)). The potential of AKS sanctions for that speech, Pfizer asserts, chills its ability to engage in the speech and presents a choice of either "relinquish[ing] its right to initiate and administer the proposed programs" or "go[ing] ahead with the programs and risk[ing] an enforcement action and the serious consequence of possible exclusion from federal health care programs." Pfizer Reply at 24.

Pfizer also cites a case outside the speech context: *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007). In that case, the Court permitted the plaintiff company to seek a declaratory judgment that a contract and patent were unenforceable and invalid respectively. *Id.* at 137. Analogizing the case to those involving potential prosecutions, the Court emphasized the

"coercion" present between the parties, *i.e.*, that the threat of an action for breach of contract was preventing the plaintiff from taking other actions. *Id.* at 129-131.

Pfizer raises at least some threat of coercion here. While the HHS OIG took no position on the Charity Program that Pfizer proposed, the Department of Justice allegedly is currently involved in cases against three other pharmaceutical companies for AKS violations stemming from donations to independent charitable foundations. *See* Pfizer Reply at 24, n.17. And AKS charges have resulted in more than $850 million in settlements from pharmaceutical companies and independent charities. *Id.* Thus, while Pfizer cannot point to any facts which specifically indicate HHS will prosecute it for AKS violations in connection with the Charity Program, it has raised a real prospect that its actions are shaped and coerced by the threat of prosecution, and the potential draconian civil penalties.

Between the allegations of coercion and the potential chilling effect on speech incident to charitable giving, Pfizer has alleged an actual case or controversy between the parties sufficient to maintain a standalone declaratory judgment claim. *See Holder*, 561 U.S. at 15-16 (actual case or controversy is present where plaintiffs stated they would begin charitable giving after the threat of prosecution was eliminated, where the government has filed prosecutions against others for the threatened violations, and where the government has not argued that these particular plaintiffs will not be prosecuted if they do what they say they wish to do.). In the circumstance present here, the Court has jurisdiction to review Pfizer's declaratory judgment claims with respect to the Charity Program.

2. Pfizer's Declaratory Judgment Claims Related to the Charity Program Do Not Satisfy the Standard for Prudential Ripeness

As noted above, a court reviews a declaratory judgment action for prudential ripeness by considering (1) the fitness of the issues for judicial decision; and (2) the hardship to the parties of

withholding court consideration. *Vullo*, 378 F. Supp. 3d at 283. While the Court has jurisdiction to consider Pfizer's declaratory judgment claim, the claim is far too remote and the facts of the underlying program are far too undeveloped to satisfy the prudential ripeness criteria. Moreover, there is no hardship alleged here that overcomes these barriers to review. As a result, the Charity Program claims are dismissed.

This is not a close case. Of course, Pfizer's claim is a purely legal question and "may be decided without further factual development." *Gary D. Peake Excavating Inc. v. Town Bd. of Town of Hancock*, 93 F.3d 68, 71-72 (2d Cir. 1996). However, HHS correctly argues that Pfizer "has only vaguely defined" the Charity Program and that the "legality of the [p]rograms depends on future facts." HHS Br. at 25; HHS Reply at 10. The record before the Court contains no details of the program other than Pfizer's unilateral description in its first unfulfilled and unreviewed request for an HHS OIG advisory opinion. *See* HHS Br. at 25 (citing AR 746, 757). OIG did not have any discussions with Pfizer regarding the program and did not request any information in connection with the Charity Program from Pfizer. And, the HHS OIG never actually gave its own views on the Charity Program. It is unclear, for example, that the HHS OIG would find that this specific program would violate the AKS or BIS or whether, after consultation with Pfizer and any resulting revisions, the program could proceed without objection from either party. While Pfizer has offered some facts here that may permit the Court to consider some of these questions, the record is still sparse as it relates to the Charity Program. Such an undeveloped record still is not "fit" for resolution by the Court. *Simmonds v. INS*, 326 F.3d 351, 359 (2d Cir. 2003) ("[I]ssues have been deemed ripe when they would not benefit from any further factual development and when the court would be in no better position to adjudicate the issues in the future than it is now." (first citing *Whitman v. Am. Trucking Ass'ns*, 531 U.S.

457, 479 (2001); and then citing *Duke Power Co. v. Carolina Env't Study Grp.*, 438 U.S. 59, 81-82 (1978))). Rather, the prudent approach is the one envisioned by the law, permitting Pfizer and the HHS OIG first to review the program and reach definitive conclusions.

The Court is cognizant that the Supreme Court specifically has cautioned against finding that claims related to pharmaceutical products are not ripe. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 153 (1967) ("[P]etitioners deal in a sensitive industry, in which public confidence in their drug products is especially important. . . . [A]ccess to the courts under the Administrative Procedure Act and the Declaratory Judgment Act must be permitted, absent a statutory bar or some other unusual circumstance . . . ."). However, in that case, the Court noted that the agency's action "purport[ed] to give an authoritative interpretation of a statutory provision that has a direct effect on the day-to-day business of all prescription drug companies; its promulgation puts petitioners in a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate." *Id.* at 152. None of these factors weigh in Pfizer's favor here. The details of the proposed program are ill-defined and vague. The HHS OIG has not purported to authoritatively determine any rights that are relevant to all companies nor even to authoritatively determine any of Pfizer's rights. Instead, the exact attributes of the Charity Program, and whether it (or the regulation of it) violates the law is "contingent on future events that may or may not occur," including Pfizer's own actions. HHS Br. at 25 (citing *In re Combustion*, 838 F.2d at 37-39). This is not a "definite and concrete" dispute, and, as a result, the Charity Program claims are unripe. In light of that, Defendants' motion to dismiss is granted as to Counts II and III of the complaint and Count I to the extent it relates to the Charity Program.

B. Pfizer's Fifth Amendment Claim Independently Fails for Lack of Standing

Pfizer's claim in Count III of the complaint that application of HHS OIG's guidance to the both the Direct Program and the Charity Program would violate the Fifth Amendment also fails because Pfizer lacks standing to assert it.

"A plaintiff has standing only if he can 'allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief.'" *California v. Texas*, __ U.S. __, 141 S. Ct. 2104, 2114 (2021) (quoting *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 (2006)). In connection with the Fifth Amendment claim, Pfizer seeks to represent not its own interests, but those of ATTR-CM patients who may lack access to tafamidis because of what it believes to be irrational economic classifications in the Medicare system. *See* Cpl. ¶¶ 135, 157. As Defendants note, a party cannot ordinarily "rest his claim to relief on the legal rights or interests of third parties." *Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004) (cited at HHS Br. at 34). Because Pfizer's claim is primarily concerned with the equal protection rights of middle-income Medicare beneficiaries, and because Pfizer is not such a person, the claim is not Pfizer's to bring.

In response, Pfizer argues that this case is similar to *Eisenstadt v. Baird*, 405 U.S. 438 (1972), where a company was allowed to bring claims on behalf of its patients using contraceptives. *Id.* at 445. However, the only law involved in that case was a statute criminalizing contraceptive production, the enforcement of which uniquely fell on the company. *Id.* Here, while framed as unique to tafamidis and the AKS, Pfizer's objection relates to the alleged impact on middle-income Medicare recipients, not on Pfizer. That impact may be common to all drugs eligible under Medicare Part D, which imposes the same co-pay requirements on all beneficiaries (*i.e.* a percentage of the cost of the drugs they are prescribed). Pfizer is not uniquely positioned to assert those rights.

Relatedly, any injury is traceable not to Pfizer's ability to organize their co-pay assistance programs, or lack of it, but instead to the Medicare Part D scheme. In order to establish standing to sue, a plaintiff must allege an injury that is "fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *California*, 141 S. Ct. at 2113 (quoting *DaimlerChrysler Corp.*, 547 U.S. at 342). The injury Pfizer raises in connection with the Fifth Amendment claim, that prohibition of the co-pay assistance programs "would discriminate on the basis of wealth without being rationally related to a legitimate government interest," Cpl. ¶ 153, is traceable not to the HHS OIG determination about Pfizer's intended co-pay programs, but is instead traceable to the statutory scheme of Medicare Part D itself. The Supreme Court directs judges to consider the precise statutory scheme from which an alleged harm arises, and to find that a plaintiff has standing to sue where the proposed remedy targets the statute responsible for it. *California*, 141 S. Ct. at 2114-16. Because Pfizer's alleged harm does not emerge from the HHS OIG guidance related to the AKS it seeks to challenge, but instead from the structure of the Medicare Part D scheme, it has not established standing to sue here.

II. DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON PLAINTIFFS' DIRECT PROGRAM CLAIMS IS GRANTED

The Court now turns to the Plaintiff's claims regarding the Direct Program. As recounted above, the HHS OIG issued an advisory opinion finding that the Direct Program could violate the AKS "if the requisite intent to induce or reward referrals for, or purchases of, items and services reimbursable by a Federal health care program were present." AR 142. The OIG found that the Direct Program appeared designed to induce "a Medicare beneficiary [who] otherwise may be unwilling or unable to purchase [tafamidis] due to his or her cost-sharing obligations, which are driven by the list price, . . . to purchase" tafamidis, leaving Medicare to "bear the costs." AR 155. Pfizer now seeks both a declaratory judgment that the Direct Program does not

violate the AKS or the BIS (Count I) and an order vacating the HHS OIG guidance and advisory opinion related to the Direct Program as contrary to law under the APA (Count IV).

Pfizer does not contend that the Direct Program would not "induce" purchases of tafamidis that otherwise might not occur. Instead, its primary argument is that, even if Pfizer's intent were to induce purchases, that intent would be insufficient to constitute a violation of the AKS. Rather, Pfizer suggests that AKS liability requires that the Direct Program be administered with a "corrupt" intent or that the payments made through the Direct Program otherwise must constitute an improper *quid pro quo* where Pfizer directly influences a doctor's or patient's decision to prescribe or purchase tafamidis. Pfizer Br. at 9-15. Pfizer then argues that because it lacks such an intent and because there is no such monetary benefit, the argument goes, the Direct Program cannot violate the AKS. Pfizer Br. at 15-16. Pfizer seeks a declaration to that effect and an order setting aside the advisory opinion as contrary to law, urging that the Direct Program never could implicate the AKS. Defendants also move for summary judgment on Pfizer's claims. For the reasons that follow, Pfizer's motion is denied, and Defendants' motion is granted.

A. The Plain Text AKS Does Not Require A Corrupt Intent or a Direct Quid Pro Quo

The Court begins with the text of the AKS. *Facebook, Inc. v. Duguid*, __ U.S. __, 141 S. Ct. 1163, 1170 (2021) ("We begin with the text"). "It is axiomatic that the plain meaning of a statute controls its interpretation, and that judicial review must end at the statute's unambiguous terms. Legislative history and other tools of interpretation may be relied upon only if the terms of the statute are ambiguous." *Lee v. Bankers Trust Co.*, 166 F.3d 540, 544 (2d Cir. 1999) (citations omitted).

The AKS provides in relevant part:

> Whoever ***knowingly and willfully*** offers or pays ***any remuneration (including any kickback, bribe, or rebate)*** directly or indirectly, overtly or covertly, in cash or in kind to any person ***to induce*** such person . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(2)(B) (emphasis added). As that text makes clear, the mental state elements of the AKS do not include a "corrupt" intent. Instead, the statute is implicated where a defendant 1) knowingly and willfully provides remuneration 2) to induce (*inter alia*) a purchase. *Id.*

1. Remuneration

Pfizer argues that "remuneration," especially read in light of the examples provided in the statute, must be narrowly construed only to include payments made with a corrupt intent. *See* Pfizer Br. at 9-12. This argument is unpersuasive. First, the plain meaning of "remuneration" includes any "payment" or "compensation, esp[ecially] for a service that someone has performed." Remuneration, BLACK'S LAW DICTIONARY (11th ed. 2019).[6] The word is not amenable to a reading that there be corruption involved.

This construction is reinforced when one considers the other words in the statute. The AKS provides in a parenthetical that "any remuneration" can "includ[e] any kickback, bribe, or rebate." 42 U.S.C. § 1320a-7b(b)(2)(B). Pfizer argues that "remuneration must be construed closely to "kickback" and "bribe," which imply corrupt intention. Pfizer Br. at 11-12. Pfizer is

[6] Black's Law Dictionary is routinely used to determine the "plain meaning" of statutory or contractual language. *See Sullivan v. Hudson*, 490 U.S. 877, 894 (1989) (citing Black's Law Dictionary for the plain meaning of the phrase "civil action"); *United States v. Davis*, 648 F.3d 84, 89 (2d Cir. 2011) (citing Black's Law Dictionary for the plain meaning of the phrase "contrary to law"); *DeMoura v. Cont'l Cas. Co.*, __ F. Supp. 3d __, 2021 WL 848840, at *5 (E.D.N.Y. 2021) (citing Black's Law Dictionary for the plain meaning of the words "direct" and "physical"); *Nasdaq, Inc. v. Exch. Traded Managers Grp., LLC*, 431 F. Supp. 3d 176, 232 (S.D.N.Y. 2019) (citing Black's Law Dictionary for the plain meaning of the phrase "royalty-bearing").

correct about the definitions of "kickback" and "bribe," both of which imply or require an illegal or immoral action. *See* Bribe, BLACK'S LAW DICTIONARY (11th ed. 2019) ("A price, reward, gift or favor given or promised *with a view to pervert the judgment of or influence the action of a person in a position of trust.*" (emphasis added)); Kickback, BLACK'S LAW DICTIONARY (11th ed. 2019) ("A sum of money *illegally paid* to someone in authority") (emphasis added). To strengthen this argument, Pfizer also cites the constructive canon of *ejusdem generis*, which provides that "[w]here general words follow an enumeration of two or more things, they apply only to persons or things of the same general kind or class specifically mentioned." Antonin Scalia & Bryan Garner, READING LAW: THE INTERPRETATION OF LEGAL TEXT 199 (1st ed. 2012); Pfizer Br. at 11-12.

This argument fails. To start, Pfizer ignores that the AKS also mandates that "remuneration" includes "rebates," the plain meaning of which implies no corrupt intention. *See* Rebate, BLACK'S LAW DICTIONARY (11th ed. 2019) ("A return of part of a payment, serving as a discount or reduction. 2. An amount of money that is paid back when someone has overpaid."). Just as Pfizer argues that "bribe" and "kickback" must inform the meaning of "remuneration," so too must "rebate." And the three example words do not share a common element of "corrupt" intent which can then be read into "remuneration."

Moreover, Pfizer's citation to the *ejusdem generis* canon is misplaced. That canon serves as a means to inform the meaning of a "general" word that *follows* more specific words. *See* Scalia & Garner, READING LAW at 199. Instead, the appropriate constructive canon here, to the extent one is necessary, is the "presumption of [a] nonexclusive 'include.'" Scalia & Garner, READING LAW at 132. This canon provides that "the verb *to include* introduces examples, not an exhaustive list," and indicates an intention "to defeat the negative-implication canon" (*i.e.* the

rule that inclusion of certain things necessarily excludes others). *Id.* at 132-33. Applying this maxim, the proper reading of the AKS text is that the parenthetical "including any kickback, bribe, or rebate" provides some, but not all of the examples of "remuneration" within the meaning of the statute. Giving the term "remuneration" its plain meaning, coupled with the non-exhaustive nature of the parenthetical and the fact that "rebate" does not imply any corrupt intention, the Court concludes that word "remuneration" should not be limited to reach only those instances that include corrupt acts.

This construction is consistent with relevant law. The Seventh Circuit, in *United States v. Borrasi*, 639 F.3d 774 (7th Cir. 2011), rejected an argument similar to the one Pfizer makes here: that a AKS defendant's "primary motivation" is what matters for liability. *Id.* at 782. In particular, the Seventh Circuit embraced the unanimous view of other Circuits at the time that "corrupt intent" is not necessary for liability under the AKS. *Id.* (citing *United States v. Greber*, 760 F.2d 68, 71 (3d Cir. 1985); and then citing *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); and then citing *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); and then citing *United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000)). In *Borassi*, employees at a medical center were convicted of AKS violations for paying kickbacks for referrals of Medicare patients. *Id.* at 777. The bribes were structured as the employees' salaries. *Id.* While the individuals were employees and performed work, at least some portion of their salary was paid in connection with referrals. *Id.* at 782. The Court rejected that the Government must prove that the "primary purpose" of the payments was corrupt and unlawful and instead affirmed the Defendants' convictions. *Id.* 782, 786. It was sufficient that the payments were made to affect decisions about medical services, and did not need to be motivated by a corrupt, unlawful, or immoral aim. While the AKS certainly includes such acts within its ambit, the plain text of the

statute is broader, encompassing any "remuneration" "to induce" a person to make a healthcare purchase or decision.

2. Inducement

Pfizer also argues that the "to induce" element in the AKS, itself implies that a corrupt intent is required or that a *quid pro quo* transaction exists. *See* Pfizer Br. at 10-13. Pfizer principally relies on an non-precedential Second Circuit summary order noting that in an AKS case "the government [i]s required to prove that any payments to middlemen were made to induce referrals in a *quid pro quo* transaction." *United States v. Krikheli*, 461 F. App'x 7, 10-11 (2d Cir. 2012). While this view may find some minimal support in other cases, it is belied by the text of the statute and other cases that examine the issue closely.

First, there is no language in the AKS proximate to or modifying "induce" that premises liability on a corrupt *quid pro quo* transaction where a benefit must flow to the requestor. The plain meaning of the word "inducement" implies a "one-way" transaction, where the requestor simply gets someone to take an action. *See* Inducement, BLACK'S LAW DICTIONARY (11th ed. 2019) ("The act or process of enticing or persuading another person to take a certain course of action."); Inducement, GARNER'S DICTIONARY OF LEGAL USAGE (3d ed. 2011) ("ordinarily means 'that which influences or persuades'"). In other words, the AKS requires only that payments are made with an intent to influence a decision about medical care or purchases, and does not require any further proof of intent or purpose. *United States v. TEVA Pharm. USA, Inc.*, No. 13 Civ. 3702 (CM), 2016 WL 750720, at *17 (S.D.N.Y. Feb. 22, 2016) ("[T]he [Government] need only prove that 'one purpose' of [the] remuneration is to induce a person to use a service for which payment is made under a federal health care program.").

Lacking support in the text of the statute, Pfizer points to the *Krikheli* summary order, in which the Second Circuit stated that a court "accurately described the law" by requiring the

Government to prove "prove that the remuneration was offered or paid as a quid pro quo in return" in an AKS prosecution. *Krikheli*, 461 F. App'x at 11. Pfizer then argues that "quid pro quo," according to precedential Circuit decisions, necessarily implies a "corrupt" intent. Pfizer Br. at 10 (citing *United States v. Alfisi*, 308 F.3d 144, 149 (2d Cir. 2002)). It first deserves mention that the case to which Pfizer points for this definition arose in the context of a bribery prosecution. The federal bribery statute specifically states that a defendant must act "corruptly." 18 U.S.C. § 201(b). Thus, it is of no importance that a case analyzing whether a *quid pro quo* bribe determined that it must have been "corruptly" made. Of more importance to this case, the AKS has no such statutory requirement.

To the extent *Krikheli* did propose such a rule of law though, it clearly is an outlier case, as no other Circuit has endorsed the narrow definition Pfizer urges here and *Krikheli* is not a precedential decision. The closest to which Pfizer points are cases emphasizing the purposes of the AKS, but not necessarily the legal requirements for liability. *See*, *e.g.*, *United States ex rel. Banigan v. PharMerica Inc.*, 950 F.3d 134, 137 (1st Cir. 2020) ("The AKS was designed to prevent medical providers from making decisions based on improper financial initiatives rather than medical necessity."); *United States ex rel. Young v. Suburban Homes Physicians*, 2017 WL 6625940, *4 (N.D. Ill. Dec. 28, 2017) (characterizing remuneration as "some unjustified, illegitimate value . . . conferred on the recipient," to conform to Congress's purpose in the AKS to prevent "provider decisions clouded by improper financial considerations").

The law is clear, however, that "[v]ague notions of a statute's 'basic purpose' are inadequate to overcome the words of its text regarding the specific issue under consideration." *Montanile v. Board of Trustees of Nat. Elevator Indus. Health Benefit Plan*, 577 U.S. 136, 150 (2016) (citing *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 261 (1993)) (alterations in original

omitted). Because the text of the statute is clear that the only showing of intent necessary for a person to be liable under the AKS is that remuneration be given "to induce" a beneficiary to purchase or receive medical services, the Court will not consider these other notions of "purpose." This approach is wholly consistent with other cases where courts have determined that the text of the AKS clearly only requires a payment intended to induce a purchase or provision of medicine or medical services. As Judge McMahon of this Court noted several years ago, judges in this District largely "follow the rule of the Third, Fifth, Seven, Ninth, and Tenth Circuits: that the [Government] need only prove that 'one purpose' of [the] remuneration is to induce a person to use a service for which payment is made under a federal health care program." *TEVA Pharm. USA, Inc.*, No. 13 Civ. 3702 (CM), 2016 WL 750720, at *17 (S.D.N.Y. Feb. 22, 2016).

The only other Circuit case to which Pfizer points in support of its position is *Guilfoile v. Shields*, 913 F.3d 178 (1st Cir. 2019). That case, however, does not support Pfizer's reading of the AKS. Instead, Pfizer's view may be endorsed by one judge on the panel concurring in part and dissenting in part from the Court's decision. The *Guilfoile* court reversed a district court's determination that consulting payments for a *bona fide* medical consultant did not implicate the AKS. *Id.* at 182-84. Specifically, the consultant worked for a medical device company, establishing relationships between the company and hospitals, which would then purchase products from the company. *Id.* The First Circuit held that the consulting payments could be illegal kickbacks in violation of the AKS, despite that the consulting fees otherwise were a valid form of compensation. *Id.* at 183-84, 194. One judge wrote separately, however, dissenting from the Court's finding of a potential AKS violation, to note that these kinds of payments were not within the "heartland" of the AKS. *Id.* at 199. That judge noted that the payments made by

the company to its consultant fell outside the core of the AKS because there was too significant attenuation between the consulting fees to the ultimate purchases by hospitals to make out inducement. *Id.* at 198. Pfizer similarly argues here that a payment falls outside this core, and therefore does not violate the AKS, absent a direct link or improper direct influence. Pfizer Br. at 11; Pfizer Reply at 3, 9. That view was not the holding of the court in *Guilfoile*, and, in any event, the concurring judge recognized that criminal statutes often expand beyond the "heartland" of their purpose. *Id* at 199 ("Of course, statutes that have cores also have peripheries. And conduct that falls within the periphery of a statute's scope is no less unlawful than conduct that falls within its core."). In sum, *Guilfoile* does not support Pfizer's contention that a "corrupt" intent or other improper direct influence on a purchasing decision is required for liability under the AKS.

In other words, the AKS means what it says. It prohibits knowingly and willfully providing remuneration which is intended to induce a purchase of medical treatments or services. While the statute is broad, that alone does not mandate that the Court must endorse a narrower reading.[7] Because its support for its position is unavailing, the Court declines Pfizer's invitation to do so here.

[7] Pfizer also argues that the AKS should be limited by application of the rule of lenity. Pfizer Br. at 13-14. That is inappropriate here. The Rule of Lenity requires ambiguity in the statute. *See Yates v. United States*, 574 U.S. 528, 547-48 (2015) ("[I]f our recourse to traditional tools of statutory construction leaves any doubt about the meaning of 'tangible object,' as that term is used in § 1519, we would invoke the rule that 'ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity.'" (quoting *Cleveland v. United States*, 531 U.S. 12, 25 (2000))). The Supreme Court also has emphasized that the rule of lenity is appropriate only where "[n]either the statute's language nor its structure provides any definitive guidance." *United States v. Thompson/Center Arms Co.*, 504 U.S. 505, 513 (1992). Breadth is not the same thing as ambiguity. *Nat'l Org. for Women, Inc. v. Scheidler*, 510 U.S. 249, 262 (1994). The Court has determined a clear plain meaning of the text of the AKS, which is not ambiguous. As a result, the rule of lenity is inapplicable here.

B. The HHS OIG Advisory Opinion Is Not Contrary to Law

Based on the plain reading of the AKS text and the relevant law, the Court now turns to the HHS OIG determination that the Direct Program could violate the AKS "if the requisite intent to induce or reward referrals for, or purchases of, items and services reimbursable by a Federal health care program were present." AR 142. This conclusion is not contrary to law, and, thus, judgment will be entered for Defendants.

As Pfizer describes the Direct Program, it is aimed to allow individuals who otherwise may not purchase tafamidis (through economic hardship, personal choice, or both) to purchase it. Pfizer Br. at 1. Because the stated intent of the payments Pfizer proposes here are to increase the number of Medicare beneficiaries who purchase the drug, the Court is unable to issue the declaratory judgment Pfizer seeks or to issue judgment in its favor on the APA claim, since the AKS prohibits all remuneration that induces purchases of drugs like tafamdis (unless the payments fall into one of the safe harbors).

The Court is not unmindful of the potential consequences of this conclusion. Pfizer makes the point that tafamidis is the only drug approved to treat ATTR-CM and made strenuous arguments to that end during argument in this case. Pfizer Br. at 1; Tr. at 60:20-62:13, 72:13-16. In theory, the AKS exists to permit doctors to prescribe the correct medication among alternatives and not because of an economic interest in prescribing one medication or another. *Cf. United States v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015) ("The Statute was enacted to protect the Medicare and Medicaid programs from increased costs and abusive practices resulting from provider decisions that are based on self-interest rather than cost, quality of care or necessity of services."). Where tafamidis is the only approved option for patients, economic hardship may result in patients with a debilitating illness foregoing treatment that otherwise might assist them.

The Government responds that an available alternative would be to lower the cost of tafamidis, which is set by Pfizer. However, as the parties discussed at length during the argument in this case, because Medicare Part D imposes cost-sharing as a percentage of a drug's price, it is impossible entirely to eliminate the financial impact of tafamidis. *See* Tr. at 45:25-47:2. And, Pfizer produces unrebutted statistics that Medicare Part D recipients sometimes forego treatment when asked to pay more than $50 due to economic hardships. Cpl. ¶ 51; Pfizer Br. at 17 n.19. It should also be noted that the Defendants' cost-saving argument is of even less persuasive value, since the off-label alternative treatments to which it points are as or more expensive than tafamidis and, in at least some circumstances, the costs would be entirely borne by the Government. Pfizer Br. at 16-17.

Still, this Court must apply the law as it currently is written and is bound by precedent and legal authority that interprets the AKS broadly and as potentially encompassing the kinds of payments Pfizer would make as part of the Direct Program. While there may be an administrative or legislative remedy to the problems Pfizer seeks to correct here, the remedy does not lie with the Court.

CONCLUSION

For the reasons stated herein, Pfizer's motion for summary judgment [ECF No. 33] is DENIED. Defendants' motion to dismiss or, in the alternative, for summary judgment [ECF No. 44] is GRANTED. With regard to the Charity Program that Pfizer intends to operate, the company's claims in Counts I, II, and III are not ripe for adjudication here and are dismissed. With regard to the Direct Program, the law is clear that absent an express carve-out, the Anti-Kickback Statute prohibits any remuneration intended to induce someone to purchase or receive a drug or medical service. No independent corrupt intent or direct *quid pro quo* is necessary. Because that is all the HHS OIG concluded when it issued an advisory opinion to Pfizer about

the Direct Program, the agency's action is not contrary to law and the Court cannot declare that the Direct Program will not violate the Anti-Kickback Statute as Pfizer requests.

The Clerk of Court respectfully is directed to close the motions at ECF Nos. 33 and 44, to enter judgment for Defendants, and to close the case.

SO ORDERED.

Date: September 30, 2021
New York, NY

MARY KAY VYSKOCIL
United States District Judge